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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,325	09/02/2003	Allan H. Graff	C75128-1	2971

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/653,325	GRAFF ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-15,17,19-31 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-15,17,19-31 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks, filed 09/21/07. Claims 3, 6, 18 and 32 are canceled. Claims 1, 2, 7, 26-28 and 31 are amended. New claim 34 is added. Claims 1, 2, 4, 5, 7-15, 17, 19-31 and 34 are pending.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 2 requires that the dosage form of claim 1, which already contains nicotine as the active agent further contain nicotine. It is unclear how the nicotine containing composition/dosage form further comprises nicotine. Clarification is respectfully requested.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 4, 5, 7-11, 13-15, 22, 26, 27 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad et al. (US 5,167,964) in view of Santus (US 6,280,761).

The amendment filed 9/21/07 in which the limitations of claim 18 is incorporated into claim 1 removes Muhammad as an anticipatory art over claims 1-11, 13-15, 22, 26, 27 and 32, which are now included with claims 17, (18 -- canceled) and 26-31 in the rejections described below.

Muhammad discloses flavored lozenges formulation and that lozenge bases are generally hard boiled candy lozenges or compressed tablet lozenges (column 8, lines 53-58). The disclosure of lozenges meets the limitation of claim 27. Muhammad specifically discloses that hard-boiled candy lozenges are amorphous or glassy (column 8, lines 59-64) meeting the limitation of claim 1a. Muhammad's formulation comprises medicaments and nicotine is specifically mentioned (column 4, lines 47 and 48) with the nicotine meeting the limitation of

claims 1c) and claims 2 and 32. The formulation comprises bulking agents, flavoring agents sweetening agents and buffers (column 8, lines 31-33; column 2, lines 60-65; column 10, lines 64-68); the buffering agents and flavoring agents meet the limitations of claims 22 and 26 and with regards to claim 26, "non-pharmacological component" is a flavor agent according to the instant specification at paragraph [0039]. The formulation may comprise 95% of a mixture sugar alcohols of sorbitol and mannitol in a ratio from about 9.5:0.5 to about 7.5:2.5 (column 9, lines 12-17) meeting the limitations of the claim 1b and the 95% sugar alcohol of Muhammad meets the limitations of claims 13-15. Claims 7 and 8 recite the properties of the dosage form of claim 1, and since a composition cannot be separated from its properties and because Muhammad discloses the dosage of claim 1, it flows that the dosage form of Muhammad possesses the properties recited in claims 7 and 8. Sufficient amount is any amount deemed sufficient by the artisan. For example, Muhammad specifically discloses that the effective amount of the medicament may vary depending on the recommended therapeutic dosage or the dose permitted for the particular medicament and that such dosages are known to the skilled artisan in the medical arts (column 5, lines 10-16). Furthermore, the formulation/dosage of Muhammad contains suspending or thickening agents such as carrageenans, xanthan gums, gelatin and celluloses, with the preferred amount of the thickener present at from about 1% to about 15% and a point within this range anticipates the recited amounts of gum in claims 9-11 and the presence of xanthan gum in the dosage of Muhammad meets the limitations of claims 4, 5 and 9-11. New claim 34 is directed to the properties of the nicotine dosage form. The nicotine is contained in the glassy matrix.

Muhammad does not teach incorporating specific amount of the nicotine in the dosage form as required by claim 1 c) as amended. But Santus prepares lozenges containing fairly low doses of nicotine in preferred amounts of 0.5 to 5 mg, and in most preferred amounts of 0.5 to 2 mg (column 6, lines 3-9). Therefore, taking the references together, one having ordinary skill in the art would be motivated to prepare nicotine containing dosage forms suitable for smoking cessation.

7. Claims 1, 17 and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad et al. (US 5,167,964) in view of Santus (US 6,280,761).

Muhammad is described above for disclosing nicotine dosage form in a glassy matrix. Many types of nicotine are known in the art as evidenced by the disclosure of Santus that nicotine polacriflex, a nicotine gum is a commercially available source of nicotine for replacement therapy (column 2, lines 8-11), meeting claim 17. Muhammad does not disclose a method of reducing nicotine craving. Santus describes a method for smoking cessation therapy, the method, comprising administering nicotine lozenge to a person in need thereof to satisfy transient craving (abstract; column 4, lines 19-28) and further discloses that lozenges containing fairly low doses of nicotine in preferred amounts of 0.5 to 5 mg, and in most preferred amounts of 0.5 to 2 mg are administered (column 6, lines 3-9), thus meeting claims 1 c) (as amended), 27, 28 and 31. Administration of the dosage form of Muhammad as modified with Santus would inherently produce blood plasma nicotine levels of claims 29 and 30. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use modified dosage form of Muhammad in which between 0.5 and 5 mg nicotine is used according to Santus

with the expectation that the low dose of the nicotine in the lozenges would satisfy transient craving, which would lead to smoking cessation according to Santus.

8. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad et al. (US 5,167,964) in view of Santus (US 6,280,761).

Muhammad is discussed above. Muhammad in view of Santus as it regards the amount of the nicotine is also described above. While Muhammad discloses the use of phosphate buffers (column 2, line 65 and column 10, lines 64-66), there is no disclosure for specific phosphate buffers. But, the buffers recited in claim 23 and the buffers of claim 24 are common phosphate and carbonate buffers that can be used interchangeably to maintain the pH of the product at the desired pH level. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the known phosphate and carbonate buffers and expect the formulation to be buffered at the desired pH.

9. Claims 12, 19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad (US 5,167,964) in view of Santus (US 6,280,761)and further in view of Rapp et al. (US 6,180,143 B1) or Burnick et al. (US 2003/0017202 A1).

Muhammad in view of Santus discloses the dosage of claim 1. The combined reference of Muhammad and Santus does not disclose the mixed sugar alcohols of claims 12 and 21. Regarding claim 25, it is noted that the dosage formulation of Muhammad comprises the sugar alcohol recited in claim 25 and the ordinary skilled artisan would know to use amounts of the sugar alcohols desired in the production of the lozenges.

However, Rapp discloses nicotine formulation that contains a sweetening agent mixture of 1.6-GPS, 1.1-GPS and 1.1-GPM (abstract; column 4, lines 38-67; claim 9), the sweetener mixture is comprised of 10-50% by weight of 1,6-GPS, 20% by weight of 1,1-GPS and 30-70% by weight of 1,1-GPM (column 2, lines 46-60; column 4, line 43-67; claims 2-5 and 14). The sweetener in Rapp and in the amounts disclosed renders obvious the sweetener of claims 12, 19 and 20. Example 3 uses ISOMALT, a sweetener that is a mixture of 1, 6-GPS and 1,1-GPM; the ISOMALT is the sugar alcohol present in claim 21. Also, Burnick discloses formulation that contains nicotine, ISOMALT and xanthan gum (abstract; paragraph [0012]; paragraph [0015].

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nicotine lozenge Muhammad as modified by the teaching of Santus. One having ordinary skill in the art would have been motivated to use mixed sugar alcohols known in the art to be formulated with nicotine according to Rapp or Burnick with the expectation of imparting low hygroscopy to the lozenge. ISOMALT is a mixture of 1,6-GPS and 1,1-GPM.

Response to Arguments

10. Applicant's arguments filed 9/21/07 as the arguments relate to the new rejections have been fully considered but they are not persuasive.

A) Applicant argues that Mohammad does not teach the present invention because Mohammad does not teach an orally dissolving, hard boiled dosage form useful for transmucosal oral administration of a nicotine active, that comprises a glassy matrix ... and from about 0.5 mg to about 5 mg nicotine active per dose, that delivers at least 50% of the nicotine via the oral mucosa prior to ingestion into the stomach.

B) Applicant argues that the drug delivery systems of Muhammad "are not in the form of hard or soft candy confection, rather they may be incorporated within such a confection."

C) Applicant argues that the dosage of Muhammad is enteric coated.

D) Applicant argues that the combination of Muhammad and Santus, Muhammad in view of Rapp or Burnick and Muhammad alone do not render obvious the claims because the combined references or Muhammad alone does not teach each and very element of the claims.

Response:

A) With regards to the amount of nicotine in the dosage form, the examiner agrees with applicant that Muhammad does not teach the recited amount and that is why the rejections of the amended claims are not made under 35 USC 102 but the rejections are made under 35 USC 103 using the teaching of Santus to provide a teaching that nicotine dosage forms containing 0.5 to 5 mg nicotine are known. Delivery of at least 50% of the nicotine via oral mucosa is the property and intended use of the dosage form with oral delivery representing route of administration of the nicotine dosage form. The nicotine of Muhammad is contained in glassy matrix as described in the rejections.

B) Applicant's recognition that the system of Muhammad can be incorporated in hard or soft candy confection supports the examiner's position that Muhammad teaches a hard boiled candy lozenges (see also column 8, lines 59-64 of Muhammad) and since the product of Muhammad is a hard candy, it meets the limitation of hard boiled dosage form of claim 1.

C) The claims have not excluded enteric coated dosages.

D) Muhammad in view of Santus, Muhammad in view of Santus and further in view of Rapp or Burnick teaches all the elements of the respective claims in the rejections because i) Santus provides a teaching of nicotine dosages that contain 0.5 to 5 mg nicotine and also teaches various of types of nicotine as described in the rejection, ii) Rapp and Burnick are relied upon for using sugar alcohols such as ISOMALT, mixtures of 1,6-GPS and 1,1-GPM with nicotine as described in the rejections. The net result is that the combination of Muhammad with Santus, and Muhammad with Santus and further with Rapp or Burnick teaches all the limitations of the claims.

No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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